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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,326	12/18/2003	Gregory R. Ott	PH 7303 DIV1	6915

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EXAMINER

DESAI, RITA J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14

Office Action Summary

Application No.

10/741,326

Applicant(s)

OTT. ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/18/2003.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

The priority to US 10/096804 and 60/275,898 has been noted.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 in part, drawn to compounds, pharmaceutical compositions and a method of treating wherein the C and B rings are a **spiro nonane**, C is a hetero ring with either O, S or N B is a carbocyclic non aromatic ring, Z is a phenyl, Ua is absent or an Oxygen, Xa is absent or a C1-C3 alkylene chain, Ya is absent and Za is bicyclic heteroring, selected from benzoimidazole, indole, dioxido, benzothiazin-4-yl, benzothiazole and benzofuran, all other R's and Q are non-hetero groups, classified in class 548, 549, 514 subclasses 407; 30,200,330,332,337,341; 409,438, 462.
A further election of e.g. 9 on page 75 was made.
- II. Claims 1-9 in part, drawn to compounds, pharmaceutical compositions and one method of treating drawn to other variations of Za, Z, Ua, Ya, C and B and A. classified in various classes and subclasses. A further election of a single disclosed species is required. This group may be subject to further restriction.
- III. Claims 10-12 drawn to different methods of treating. May be subject to restriction.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different cores with different groupings and hence different bonding and properties.

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are several drugs available that treat other diseases such as glaucoma, tumor growth and such.

Hence restriction is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Belfield on 8/4/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 in part, drawn to compounds, pharmaceutical compositions

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and a method of treating wherein the C and B rings are **spiro nonane** , C is a hetero ring with either O, S or N B is a carbocyclic non aromatic ring, Z is a phenyl, Ua is absent or an Oxygen, Xa is absent or a C1-C3 alkylene chain, Ya is absent and Za is bicyclic heteroring, selected from benzoimidazole, , indole, dioxido, benzothiazin-4-yl , benzothiazole and benzofuran , all other R's and Q groups are non-hetero ring containing classified in class 548, 549, 514 subclasses 407; 30,200,330,332,337,341; 409,438, 462.

A further election of eg. 9 on page 75 was made.

Affirmation of this election must be made by applicant in replying to this Office action. Claim s 1-9 drawn to group II are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the cancelled non-elected subject matter, without prejudice in due course.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Scope of Enablement.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some R2, R3 R2a substituents, does not reasonably provide enablement for any and all the A, Re, R2, R3, Rb, Rc's, 2 Rc together forming a spiro ring and hetero rings, R6 and such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims without any undue burden.

In re Wands, 858 F.2d 731,737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

The breath of the claims is so vast and applicants have provided only 67 example with very limited number of substituents.

The A, Re, R2, R3, Rb, Rc's, 2 Rc together forming a spiro ring, R6 have so many variances, and art of treating diseases is so specific since it acts via a lock and key mechanism, there is **very little predictability in the art**, that every substituent from a carbocyclic ring to a H to a acid or amido group, in a certain position would react in the same way.

The applicants have provided **very little guidance** for these substituents.

The only A group that the applicants have shown is the -C=ONH or -C=OOR.

There is no guidance for the sulfur or phosphorous containing moieties.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. The limited number of examples for R10 and only hydrogen for Re, and for the R2, R3 and other variables does not convey to one skill in the art the whole scope of the compound.

The specifications simply state a laundry list of different varied substituents and has exemplified only a few substituents. There is no guidance for compounds wherein Rc is together a cyclo ring and for the sulfur or phosphorous containing moieties of A.

In general the whole specification does not convey to one skilled in the art that the inventor, at the time the invention was filed had possession of the claimed invention encompassing the whole scope of the compounds.

Conclusion

The claims 1-9 drawn to the elected group are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684.

The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
August 5, 2004

RJ Desai
8/5/04